STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

Department of Human Services
DIVISION OF HEALTH CARE QUALITY,
FINANCING AND PURCHASING
Center For Child and Family Health
600 New London Avenue
Cranston, Rhode Island 02920
Telephone: 462-3113 Fax: 462-6353

MEMORANDUM

June 30, 2005

TO: Patrice Cooper (UHC)
Gilson DaSilva (BCBS)
Ron Barnett (NHPRI)

FROM: Tricia Leddy
Administrator, Center for Child and Family Health

SUBJECT: **Policy Clarification: Coverage of Experimental Drugs/Procedures**

Under Federal regulations, State Medicaid programs may cover any medically necessary service as long as it is covered under the Social Security Act (Act). The Act specifically prohibits coverage of experimental drugs or procedures. Therefore, a State Medicaid agency cannot receive Federal-matching funds for payment of non-FDA approved drugs. It should be noted that Attachment C to the *RIte Care Health Plan Contract* is explicit that "experimental" items are "non-covered services" under the contract. This limitation has been in effect since the beginning of RIte Care.

According to Federal regulations, once a managed care organization (MCO) receives a capitation payment from the State Medicaid agency (the Department of Human Services, or DHS, in the instance of Rhode Island) or the agency's representative, the money loses its identity as Federal Medicaid funding (see attached). **As such, if an MCO determines that a non-covered service is medically necessary, it has the authority to provide that service or to authorize payment for it out of the MCO's administrative costs or profits (see the attached 42 CFR 438.6(e)).** It should be noted that this Federal regulatory provision is incorporated into Section 2.06.01 of the *RIte Care Health Plan Contract* that has been in effect since January 1, 2005.

If an MCO provides or pays for an experimental drug or procedure, it does so at its own risk and the State will be held harmless by an MCO that does so under the provisions of Section 3.05.07 of the *RIte Care Health Plan Contract.*

Please communicate this information within your organization as appropriate.

Cc: Deborah Florio
Lissa DiMauro
Rick Jacobsen
Murray Brown,
Renee Rulin, MD
Janine Zuromski

(iii)TheState'sprojectionofexpenditures under its previous year's contract (or under its FFS program if it didnothaveacontractinthepreviousyear) compared to those projected underthepropoSedcontract.

(iv) An explanation of any incentive arrangements, or stop-loss, reinsurance, or any other risk-sharing methodologiesunderthecontract.

(5) *Specialcontractprovisions.* (i) Contract provisions for reinsurance, stop-loss limits or other risk-sharing methodologies must be computed on an actuariallysoundbasis.

(ii) If risk corridor arrangements result in payments that exceed the approved capitation rates, these excess payments will not be considered actuarially sound to the extent that they result in total payments that exceed the amount Medicaid would have paid, on a fee-for-service basis, for the State plan services actually furnished to enrolled individuals, plus an amount for MCO, PIHP, or PAHP administrative costs directly related to the provision oftheseservices.

(iii) Contracts with incentive arrangements may not provide for payment in excess of 105 percent of the approved capitation payments attributable to the enrollees or services covered by the incentive arrangement, since such total payments will not be consideredtobeactuariallysound.

(iv) For all incentive arrangements, the contract must provide that the arrangementis—

(A)Forafixedperiodoftime;

(B)Nottoberenewedautomatically;

(C)Madeavailabletobothpublicand privatecontractors;

(D) Not conditioned on intergovernmentaltransferagreements;and

(E)Necessaryforthespecifiedactivitiesandtargets.

(v)IfaStatemakespaymentstoproviders for graduate medical education (GME) costs under an approved State plan, the State must adjust the actuarially sound capitation rates to account for the GME payments to be made on behalf of enrollees covered under the contract, not to exceed the aggregate amount that would have been paid under the approved State plan for FFS. States must first establish actuarially sound capitation rates prior to making adjustments for GME.

(d) *Enrollment discrimination prohibited.* Contracts with MCOs, PIHPs, PAHPs, and PCCMs must provide as follows:

(1) The MCO, PIHP, PAHP, or PCCM accepts individuals eligible for enrollment in the order in which they apply without restriction (unless authorized by the Regional Administrator), up to thelimitssetunderthecontract.

(2)Enrollmentisvoluntary,exceptin the case of mandatory enrollment programs that meet the conditions set forthin§438.50(a).

(3) The MCO, PIHP, PAHP, or PCCM will not, on the basis of health status or need for health care services, discriminate against individuals eligible toenroll.

(4) The MCO, PIHP, PAHP, or PCCM will not discriminate against individuals eligible to enroll on the basis of race, color, or national origin, and will notuseanypolicyorpracticethathas the effect of discriminating on the basis of race, color, or national origin.

(e) *Services that may be covered.* An MCO, PIHP, or PAHP contract may cover,forenrollees,servicesthatarein addition to those covered under the State plan, although the cost of these servicescannotbeincludedwhendetermining the payment rates under §438.6(c).

(f) *Compliance with contracting rules.* All contracts under this subpart must:

(1) Comply with all applicable Federal and State laws and regulations including title VI of the Civil Rights Act of 1964; title IX of the Education Amendments of 1972 (regarding education programs and activities); the Age Discrimination Act of 1975; the Rehabilitation Act of 1973; and the Americans with Disabilities Act; and

(2) Meet all the requirements of this section.

(g) *Inspection and audit of financial records.* Risk contracts must provide that the State agency and the Department may inspect and audit any financial records of the entity or its subcontractors.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Care Financing Administration

Center for Medicaid and State Operations
7500 Security Blvd.
Baltimore, MD 21244-1850

JUN 24 1998

Dear State Medicaid Director:

A policy concern relating to certain contract requirements on managed care organizations (MCOs) or prepaid health plans (PHPs) has been undergoing Administration review. This is to inform you how we have considered this issue and what decision we have reached.

Some States have required in their contracts with MCOs or PHPs that any savings within their capitated payment, minus an allowed profit, if any, be used to provide health services to persons who are not eligible for Medicaid.

We view this practice as an inappropriate subsidy for services for the uninsured. (See section 1903(m)(2)(A)(iii) of the Social Security Act, which states that capitated programs are intended for Medicaid recipients.)

However, we recognize that when a capitated payment is made to an MCO or a PHP, the entity is required to meet its contractual obligations to serve Medicaid beneficiaries within the money provided, and that except for limits that may be set on allowed profits (in for-profit entities), the MCO or PHP can use its savings as it wishes. In effect, it is no longer "Medicaid money." In fact, should an MCO or PHP voluntarily choose to serve people who are not Medicaid eligible, it is free to do so. However, we believe it is not appropriate for the State Medicaid agency to require in its contract with an MCO or PHP that savings from capitated payments be used to provide health services to individuals not otherwise eligible for Medicaid.

Therefore, for any new or pending section 1915(b) or 1115 waivers (including applications for renewals) or any other Medicaid managed care situation (e.g., State plan option under the Balanced Budget Act), as a matter of policy, we will not approve any State Medicaid agency waiver application that contains a requirement for MCOs or PHPs to use savings under the capitation rate for non-Medicaid eligibles. Furthermore, in our normal review of waivers,

Requests for Proposals, and contracts, we will also ascertain whether or not States are in compliance with this policy directive.

If you have any questions about this policy, please contact Wayne Smith at (410) 786-6762.

Sincerely,

Sally K. Richardson
Director

cc: All HCFA Regional Administrators

All HCFA Associate Regional Administrators
for Medicaid and State Operations

Lee Partridge
American Public Welfare Association

Joy Wilson
National Conference of State Legislatures

Jennifer Baxendell
National Governors' Association